Dockets Management Staff
Food and Drug Administration
5630 Fishers Lane Rm 1061
Rockville MD 20852

December 4, 2023

**Re: Docket No. FDA-2023-N-2177**
**Medical Devices; Laboratory Developed Tests**

Dear Sir or Madam:

These comments are submitted on behalf of The Blood Profiling Atlas in Cancer (BLOODPAC) Consortium. BLOODPAC was launched on October 17, 2016 as a commitment to the first White House Cancer Moonshot to accelerate the development, validation and clinical use of liquid biopsy assays to better inform medical decisions and improve patient care and outcomes. BLOODPAC has established a collaborative infrastructure to develop standards and best practices, organize and coordinate research studies through its members and operate the BLOODPAC Data Commons (BPDC) to support the exchange of raw and processed data generated by the liquid biopsy research community.

In addition to developing standards and aggregating data, BLOODPAC works collaboratively with all stakeholders in the field to broaden awareness and implementation of the suggested guidelines and establish a wider chain of feedback and discussion in the community. BLOODPAC's unique approach to collaboration in the field has led to the organization's success and helps to guide our work into the future.

BLOODPAC appreciates the opportunity to provide comments and input on the document, *Medical Devices; Laboratory Developed Tests*. BLOODPAC believes it is important for the Agency to provide a flexible and least burdensome framework for LDT manufacturers. We acknowledge that this new policy direction represents a significant undertaking, and we stand ready to collaborate with the Agency and offer expertise to help address concerns around the best approach to implement changes in the existing regulatory framework.

The goals of BLOODPAC, which include having well-designed and validated liquid biopsy tests for patient care, apply to any regulatory paradigm or diagnostic model (LDT and IVD). BLOODPAC has specifically been working closely with a number of departments within the Agency including OHT7, OCE, personalized medicine staff and others resulting the in the publication of protocols such as our generic protocols for the analytical validation of NGS based ctDNA assays. In addition, BLOODPAC regularly holds webinars to advance the field of liquid

biopsy development such as clinical and analytical validation. We firmly believe that collaborative groups, such as BLOODPAC, could offer resources to help the Agency and laboratories arrive at an appropriate least burdensome approach that permits innovation in the diagnostic space. We look forward to engaging with the Agency in the future on these topics.

Thank you for considering our views.

Respectfully,

Lauren Leiman
Executive Director
BLOODPAC